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March 17, 1999

Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane Room 1061 Rockville, MD 20852 [Docket No. 98P-0504]

To Whom It May Concern:

I wish to hereby state my objection to the petition by the <u>Center For Science In The Public Interest</u> to "require that shellfish sold for raw consumption be free of the bacteria, called Vibrio vulnificus." The petition goes on to indicate that treatment is available to eradicate the bacteria; citing 89 deaths since 1989, and a danger for "one in nine Americans with certain medical conditions."

While there is a human health risk associated with the consumption of raw molluscan shellfish harvested from any waters, the risk is negligible. Statistics do not bear out the "one-in-nine" risk referenced in the petition. The actual risk is less than that associated with driving an automobile, walking inner-city streets, boating, etc. I believe our charge in the Interstate Shellfish Sanitation Conference (ISSC) is to foster a system that establishes a minimal, acceptable risk, and provides constructive notice to the public regarding that risk. I do not believe it is the charge of the Federal Government to attempt to make life risk-free (an impossible and invasive undertaking).

Additionally, I strongly object to the lack of due process, as represented by the petition. This is clearly a matter for the ISSC to address.

Please contact me at 302-739-4590 if you have any questions.

Thank you for your attention to this matter.

Regards,

Jack Pingree

Manager

Shellfish and Recreational Water Branch

State of Delaware

98P-05UY

cc: Ken Moore, ISSC Executive Director
Mark Bryan

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STATE OF DELAWARE DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENTAL CONTROL

DIVISION OF WATER RESOURCES WATERSHED ASSESSMENT SECTION 820 SILVER LAKE BOULEVARD, SUITE 220 DOVER, DELAWARE 19904-2464

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